(2)

No. 92-453

Supreme Court, U.S.
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In The

Supreme Court of the United States

October Term, 1992

ANTHONY MAZUR and EDNA MAZUR
as Parents and Guardians of
LISA MARIE MAZUR, a Minor, and
ANTHONY MAZUR, and EDNA MAZUR,
in their own right,

Petitioners,

v.

MERCK & CO., INC.,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Third Circuit

RESPONDENT'S BRIEF IN OPPOSITION

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COUNTER-STATEMENT OF QUESTION PRESENTED FOR REVIEW

Whether the Court of Appeals correctly followed long-established precedent of the Pennsylvania Supreme and Superior Courts in holding that the scope of a vaccine manufacturer's duty to warn of possible health risks associated with its product is governed by the "reasonableness" standard of Section 388 of the Restatement (Second) of Torts, and in holding that respondent Merck satisfied its duty by providing to the Centers for Disease Control adequate information concerning the vaccine and by contractually obligating that agency to communicate the risks and benefits of the vaccine to vaccinees.

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RESPONDENT'S BRIEF IN OPPOSITION

Respondent Merck & Co., Inc. ("Merck")[1] respectfully requests that this Court deny the petition for a writ of certiorari.

[1] A listing of Merck's subsidiaries and joint ventures as required by Rule 29.1 of this Court are set forth in the appendix.

OPINIONS BELOW

The opinions below are reproduced in the appendix to the petition.

COUNTER-STATEMENT OF THE CASE

In the late 1970's, more than 2000 children in Philadelphia contracted measles during two major outbreaks of the disease. In response, the Philadelphia Department of Public Health required that all school children be vaccinated against a variety of pediatric diseases. As part of the City's effort, Robert G. Sharrar, M.D. of the Health Department developed a school-based vaccination program, with the assistance, *inter alia*, of the United States Centers for Disease Control ("CDC"). The Health Department selected the vaccines to be administered in the program and determined which students should receive each of them. Dr. Sharrar selected M-M-R® II ("M-M-R II") as the vaccine for simultaneous vaccination against measles, mumps, and rubella (German measles).

Since 1978, Merck has been licensed by the United States Food and Drug Administration ("FDA") to manufacture and distribute M-M-R II. The FDA approved the packaging and labeling of the vaccine. A package circular describing the risks associated with the vaccine's use, and other information concerning the vaccine, was and is distributed with each vial of M-M-R II. At the time of Lisa Mazur's vaccination in 1983, the package circular included the following information concerning subacute sclerosing panencephalitis ("SSPE"):

> There have been reports of subacute sclerosing panencephalitis (SSPE) in children who did not have a history of natural measles but did receive measles vaccine. Some of these cases may have resulted from unrecognized measles in the first year of life or possibly from the measles vaccination. Based on estimated nationwide measles vaccine distribution, the association of SSPE cases to measles vaccination is about one case per million vaccine doses distributed. This is far less than the association with natural measles, 5-10 cases of SSPE per million cases of measles. The results of a retrospective case-controlled study conducted by the Center for Disease Control suggest that the overall effect of measles vaccine has been to protect against SSPE by preventing measles with its inherent higher risk of SSPE.

This statement was based on a study undertaken by the CDC and was approved by the FDA.

The Health Department acquired M-M-R II from the CDC pursuant to a grant. The CDC purchased the vaccine from Merck pursuant to a series of contracts between it and Merck. Each of these contracts contained a "duty to warn" paragraph, which in pertinent part, obligated the CDC to

> (1) take all appropriate steps to assure that all vaccine supplied . . . pursuant to the terms of this contract, shall be administered to each patient on the basis of an individualized medical judgment by a physician, or (2) take all appropriate steps to provide to such patient (or to the patient's parent or guardian) meaningful warnings relating to the risks and benefits of

> vaccination, in form and language understandable to such patient, parent or guardian.

In order to fulfill its obligations under this paragraph, the CDC prepared an "Important Information Statement", which contained information on the risks and benefits of the vaccine. The CDC required every health agency which obtained M-M-R II from it pursuant to a grant, including the Philadelphia Health Department, to distribute the Important Information Statement to the vaccinees or their parents. The Important Information Statement was sent to parents of school age children in Philadelphia.

Although it is undisputed that the School District distributed the Important Information Statement, Lisa's mother contends she never received it. However, she does admit being notified of the vaccination program, and recalled receiving from the School District a letter with an attached vaccination record and permission form. Mrs. Mazur contends that she neither signed nor returned the permission form.

Lisa received M-M-R II on February 26, 1982 at her school. Edith Frederick, R.N., was responsible for the vaccination program at Lisa's school and oversaw the administration of M-M-R II to Lisa and her classmates.

On November 2, 1983, Lisa was diagnosed as having SSPE. Lisa's treating physician does not believe that M-M-R II caused Lisa's condition. Similarly, a pediatric neurologist who provided a second opinion to the Mazurs does not believe M-M-R II caused Lisa's condition.

Despite these medical opinions, in October, 1985, the Mazurs commenced a civil action in the Court of Common Pleas, Philadelphia County, Pennsylvania against Merck alleging that M-M-R II was defective and that it caused Lisa to develop SSPE. Based on diversity of citizenship, Merck removed the action to the United States District Court for the Eastern District of Pennsylvania.

Almost four years later, Merck filed a Motion for Summary Judgment. On June 29, 1990, the District Court granted the motion in part and denied it in part. *Mazur v. Merck & Co.*, 742 F. Supp. 239 (E.D. Pa. 1990). The District Court denied the motion with respect to the federal preemption and statute of limitation defenses. *Id.* at 266. It held, however, that under the "learned intermediary rule", Merck had a duty to provide warnings only to the health care profession and that the "mass immunization" exception to that rule did not apply in this case. *Id.* at 255-56. The District Court further found that the package circular was adequate in a number of respects, but reserved judgment on certain other "duty to warn" issues. *Id.* at 266.

Following sixty days of additional discovery on the duty to warn claims, Merck filed a Supplemental Motion for Summary Judgment.[2] On June 27, 1991, the District Court granted Merck's motion. *Mazur v. Merck & Co.*, 767

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[2] The parties stipulated in writing that Merck would not seek summary adjudication on the issue of medical causation, that the Mazurs had no evidence that M-M-R II was defectively designed or manufactured, and that all of the Mazurs' claims were predicated on the allegation that Merck failed to provide adequate warnings.

F. Supp. 697 (E.D. Pa. 1991). The District Court held that Merck met its duty to warn by providing an adequate warning to a "learned intermediary" (the nurse who administered the program at Lisa's school), and, in the alternative, that Merck exercised reasonable care to inform users of the risks of its vaccine by contractually obligating the CDC to warn vaccinees directly. *Id.* at 715.

On May 20, 1992, the Court of Appeals for the Third Circuit affirmed the District Court's decision to grant summary judgment. In an opinion by the Honorable Anthony J. Scirica, the Court of Appeals, after an analysis of existing Pennsylvania law, held that a vaccine manufacturer's duty to warn is judged under the "reasonableness" standard of Section 388 of the Restatement (Second) of Torts, and that Merck satisfied its duty by providing to the CDC adequate information concerning the risks of Merck's vaccine and by contractually obligating that agency to communicate the risks to vaccinees. *Mazur v. Merck & Co., Inc.*, 964 F.2d 1348, 1353-55, 1369 (3d Cir. 1992).[3]

On June 18, 1992, the Mazurs' petition for rehearing and rehearing *en banc* was denied by the Court of Appeals.

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[3] The Court of Appeals, however, disagreed with the District Court's conclusion that Nurse Frederick acted as a "learned intermediary". 964 F.2d at 1360. Because the court concluded that Merck satisfied any duty it had to warn users directly, it was not necessary to decide whether the Pennsylvania Supreme Court would adopt the "mass immunization" exception to the "learned intermediary" rule. Nonetheless, the Court of Appeals concluded for purposes of its analysis that the "mass immunization" exception applied in this case. *Id.* at 1361 n.20, 1364, 1369.

PETITIONERS' WRIT OF CERTIORARI SHOULD BE DENIED

The only issue raised by the Petition is whether the Court of Appeals correctly interpreted and applied the products liability and negligence laws of the Commonwealth of Pennsylvania. The Petition thus raises only state law questions on which this Court has traditionally deferred to the Courts of Appeals. Moreover, the lower court's decision was manifestly correct in its application of established Pennsylvania law.

There is no proper basis for the Petition for Writ of Certiorari. This is not a case involving a federal question. Nor is this a situation where a court of appeals has rendered a decision in conflict with the decision of another court of appeals on the same matter. The Court of Appeals has not departed from the accepted or usual course of judicial proceedings, thereby calling for an exercise of the Supreme Court's power of supervision. SUP. CT. RULE 10. In short, there are no special and important reasons supporting the request for certiorari in this case.

A. The Petition Raises Only State Law Questions On Which This Court Has Traditionally Deferred To The Courts Of Appeals; Moreover, The Court of Appeals Correctly Applied Pennsylvania Law.

This Court has traditionally deferred to lower federal courts on questions of state law unless the decision is clearly erroneous or there is plain error. *Brockett v.*

Spokane Arcades, Inc., 472 U.S. 491, 500 n.9 (1985).[4] As the Court stated in *Haring v. Prosise*, 462 U.S. 306 (1983):

> We emphasize, however, that, standing alone, a challenge to state-law determinations by the Court of Appeals will rarely constitute an appropriate subject of this Court's review.

Id. at 314 n.8.

The primary reason for this deference is that federal judges who deal regularly with state law questions are in the best position to determine how local state courts would dispose of comparable issues. *Butner v. U.S.*, 440 U.S. 48, 58 (1979). In fact, this Court has accepted interpretations of state law in which the district court and court of appeals have concurred even if an examination of the state law issue without such guidance might have justified a different conclusion. *See Haring*, 462 U.S. at 314 n.8; *Bishop v. Wood*, 426 U.S. 341, 346 (1976).

The Petition for Certiorari involves only the law of Pennsylvania. A Pennsylvania District Court Judge of long experience and three Circuit Judges whose circuit includes Pennsylvania concurred in the application of Pennsylvania law which Petitioners have challenged. Nothing in the Petition properly supports a request that

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[4] In 1980, the Court restated the considerations governing review on certiorari in Rule 17.1, a predecessor to the current Rule 10. When revising the Rule, the Court deleted a long-standing provision that had previously listed a decision by a Court of Appeals resolving "an important state or territorial question in a way in conflict with applicable state or territorial law", as a reason to consider granting certiorari. STERN, GRESSMAN & SHAPIRO, SUPREME COURT PRACTICE at 212 (6th ed. 1986).

this Court review the unanimous interpretation of state law by four lower court federal judges. Indeed, not only is the Court of Appeals' decision thoughtful and well-reasoned, but it also faithfully follows the holdings of the Pennsylvania Supreme Court.

Petitioners' statement that the Court of Appeals had "no clear precedent" on which to base its opinion, PET. FOR WRIT OF CERT. at 8, is quite simply untrue. On the contrary, the Court of Appeals' decision was based on long-standing and consistent holdings of the Pennsylvania Supreme and Superior Courts that dealt clearly and explicitly with the parameters of a pharmaceutical manufacturer's duty to warn.[5]

The seminal case is the Pennsylvania Supreme Court's decision in *Incollingo v. Ewing*, 282 A.2d 206 (Pa. 1971). There, the Pennsylvania Supreme Court explained that ordinarily Pennsylvania follows Section 402A of the Restatement (Second) of Torts which imposes strict liability on the manufacturer of a product sold in a defective condition unreasonably dangerous to the user or consumer. The Court held, however, that these principles of Section 402A do not apply to "failure to warn" claims involving prescription drugs, which are "unavoidably unsafe products" within the meaning of comment k to Section 402A. Instead, for such products, the standard of care as defined by Section 388 of the Restatement is

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[5] Reference is primarily made to the Court of Appeals' decision, particularly at 964 F.2d at 1353-55, 1364-66, for the court's reasoning on this issue. A brief summary, however, is given against the backdrop of certain arguments made by Petitioners.

applied. Under this section, the manufacturer has a duty to exercise "reasonable care" to inform those for whose use the article is supplied of the facts that make it likely to be dangerous. *Incollingo*, 282 A.2d at 220 n.8. *See also* 964 F.2d at 1353-55. Thirteen years later, the Pennsylvania Supreme Court reaffirmed the *Incollingo* holding in *Baldino v. Castagna*, 478 A.2d 807, 810 (Pa. 1984).

The Court of Appeals believed that there was nothing unclear or unsettled concerning the applicable Pennsylvania law and stated that "because the M-M-R II vaccine is an 'unavoidably unsafe product', we believe *Incollingo* is controlling here." 964 F.2d at 1354. The Court of Appeals further recognized that "at least in cases involving 'unavoidably unsafe products', the Pennsylvania Supreme Court has not distinguished between a prescription drug manufacturer's duty to warn in negligence versus strict liability." *Id.* at 1355 n.8.

Petitioners urge here, as they did below, that *Incollingo* and *Baldino* are inapposite because they involved negligence rather than strict liability causes of action. However, as the Court of Appeals noted, the court's reasoning in *Incollingo* was based on its analysis of the proper rules under section 402A with regard to "unavoidably unsafe products," not on the absence in that case of a strict liability failure to warn claim.[6] This has certainly been the understanding of the Pennsylvania

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[6] Significantly, not one of the cases cited by Petitioners in support of their proposition that under Pennsylvania law negligence concepts have no place in strict liability failure to warn analysis involves prescription drugs or other "unavoidably unsafe products" as defined by comment k.

Superior Court, which has uniformly applied the *Incollingo/Baldino* holding in numerous cases involving a pharmaceutical manufacturer's duty to warn. *See White v. Weiner*, 562 A.2d 378, 384 (Pa. Super. Ct. 1989), *aff'd without op.*, 583 A.2d 789 (Pa. 1991); *McDaniel v. Merck, Sharp & Dohme*, 533 A.2d 436, 445-46 (Pa. Super. Ct. 1987), *Makripodis v. Merrell-Dow Pharm. Inc.*, 523 A.2d 374, 377 (Pa. Super. Ct. 1987). *See also Hahn v. Richter*, No. 00019, Phila., 1992 Pa. Super. LEXIS 275 (Pa. Super. Ct., Feb. 13, 1992), *reh'g granted*, May 1, 1992. It is noteworthy that the Petition for Certiorari does not cite to a single failure to warn case involving a prescription drug or "unavoidably unsafe product" that contradicts the law as applied by the Court of Appeals.

The Court of Appeals also applied Section 388 of the Restatement in deciding whether Merck reasonably relied on the CDC's contractual guarantee that M-M-R II would be administered by a physician or only after a meaningful warning had been provided to the vaccinees or their parents. In evaluating Merck's duty to warn under Section 388, the court turned to the comments to this section that provide that a manufacturer may meet its duty to warn by entrusting the communication of that warning to a third person.[7] 964 F.2d at 1367-69. Accordingly, the

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[7] *Berkebile v. Brantly Helicopter Corp.*, 337 A.2d 893, 903 (Pa. 1975), is inapposite as it did not involve the application of duty to warn concepts to an "unavoidably unsafe product".

Petitioners also cite to the "mass immunization" rule for the proposition that Merck had a duty to warn directly vaccinees or their parents. PET. FOR WRIT OF CERT. at 16. Petitioners misstate that rule. The "mass immunization" exception provides that "it is the responsibility of the manufacturer to see that warnings

Court of Appeals correctly concluded, based on established law, that Merck had satisfactorily fulfilled its duty to warn.[8]

B. The Court Of Appeals Acted Correctly In Deciding The Case Before It On The Basis Of Settled Pennsylvania Law.

Petitioners raise an "abstention" issue for the first time in their Petition for Writ of Certiorari. "Where issues are neither raised before nor considered by the Court of Appeals, this Court will not ordinarily consider them." *Adickes v. Kress & Co.*, 398 U.S. 144, 147 n.2 (1970). Only in exceptional circumstances will such issues be reviewed. *Youakim v. Miller*, 425 U.S. 230, 234 (1976). *Compare City of Houston, Texas v. Hill*, 482 U.S. 451, 467 n.16 (1987). Merck seriously questions whether Petitioners should be able to raise this issue at this time. However, even if Petitioners

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reach the consumer, either by giving warning itself or by obligating the purchaser to give warning." *Davis v. Wyeth Laboratories*, 399 F.2d 121, 131 (9th Cir. 1968). This is exactly what Merck did here. In effect, Petitioners asked the courts below to adopt "half" of the "mass immunization" exception.

[8] Because the Court of Appeals held that Merck satisfied its duty to warn as a matter of law, it did not reach the question of proximate causation. 964 F.2d at 1352 n.3. Petitioners have always contended that Lisa was vaccinated over her parents' objections. If, in fact, Lisa's parents never consented to her vaccination, it is difficult to conceive how any alleged failure to warn by Merck could have proximately caused Lisa's vaccination or her injuries. In any event, Merck does not concede that M-M-R II, in fact, caused Lisa Mazur's SSPE.

could properly raise the issue before this Court, their arguments are meritless.

It is the duty of a federal court sitting in diversity to decide questions of state law in rendering judgment. Abstention from this duty is the exception, not the rule. It is an extraordinary, limited and narrow exception. *Colorado River Water Conservation Dist. v. U.S.*, 424 U.S. 800 (1976). As this Court determined in *Meredith v. City of Winter Haven*, 320 U.S. 228 (1943), it is inappropriate for a federal court sitting in diversity to defer or decline its decision in a wholly state law case merely because the answers to questions of state law are difficult or uncertain. *Id.* at 234-35. In this case, the questions of state law are not even "difficult" or "uncertain." The state law is settled. *See supra* pp. 7-11. There is no reason, then, to require the Court of Appeals to "defer" making its decision on a case that is properly before it.

Petitioners seek to deviate from this Court's established policies, thereby creating a new procedure on how and when federal courts sitting in diversity should render judgment. Petitioners ask this Court to require the Court of Appeals to wait for a ruling on a similar issue from a state intermediate appellate court, when the Pennsylvania Supreme Court already has squarely addressed the same issue. In support of such a request, Petitioners rely on the possibility that the Superior Court *en banc* might overturn the panel's decision in *Hahn v. Richter*, No. 00019, Phila., 1992 Pa. Super. LEXIS 275 (Pa. Super. Ct., Feb. 13, 1992), *reh'g granted*, May 1, 1992, going so far as

to predict its reversal.[9] Assuming, *arguendo*, that the Superior Court did overturn *Hahn*, that decision would not be binding on the Court of Appeals. *Commissioner v. Estate of Bosch*, 387 U.S. 456, 465 (1967). Would the Court of Appeals then be required to stay further its decision until disposition of the inevitable appeal to the Pennsylvania Supreme Court? The same argument as is here made by Petitioners could be urged to require a federal court sitting in diversity to "defer" its decision whenever a case involving similar issues is pending, at any stage, in the state court system. The adoption of such arguments would unduly delay federal court decision-making and interfere with the proper exercise of diversity jurisdiction.

The Court of Appeals did not abuse its discretion in deciding the case before it based on what it believed was controlling authority by the Pennsylvania Supreme Court. Indeed, the Court of Appeals was obligated to decide rather than defer the case.[10]

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[9] Petitioners' prediction as to the Superior Court's decision is speculative at best. The majority in *Hahn* applied the same analysis and reached the same conclusion on the duty to warn issue as the District Court and the Court of Appeals. Furthermore, a grant of rehearing by the Superior Court gives absolutely no indication as to what the Pennsylvania Supreme Court might decide.

[10] Similarly, traditional doctrines of abstention do not afford any relief to Petitioners. The present case involves state common law claims and the state law to be applied is settled. There is no federal constitutional question that might be mooted or presented in a different posture by a state court determination of pertinent state law. *See, e.g., Railroad Comm'n of Texas v. Pullman Co.*, 312 U.S. 643 (1941). Federal jurisdiction in this case

C. The Court of Appeals' Decision, Correctly Applying Pennsylvania Law, Will Not Preclude Future Plaintiffs From Obtaining Proper Redress.

It is the judicial function to decide whether the particular plaintiff, on the particular facts before the court, is entitled to redress from the particular defendant. Drawing all inferences against respondent Merck, the Court of Appeals, as discussed above, applied established Pennsylvania law, and determined that Petitioners were not entitled to recovery for their claims on the specific facts of this case. The practical effect of the Court of Appeals' decision is no different from that of any other court decision.

Petitioners' assertion that the Court of Appeals' decision forecloses any redress for possible claims from future vaccine-related injuries is otherwise flawed. In 1987, Congress passed the National Childhood Vaccine Injury Program (the "Act"), 42 U.S.C. §§ 300aa-10, *et seq.* The Act provides a no fault system of compensation in

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has not been invoked to interfere or restrain the state court from proceeding in litigation with the same parties on the same issues. *See, e.g., Younger v. Harris,* 401 U.S. 37 (1971). Nor does the case involve a difficult question of state law which bears on policy problems in which the federal court's action would disrupt the state's interests. *See, e.g., Colorado River Water Conservation Dist. v. U.S.,* 424 U.S. 800 (1976); *Louisiana Power & Light v. Thibodaux,* 360 U.S. 25 (1959). This case also does not involve parallel state and federal suits between the same parties where exceptional circumstances might justify a stay or dismissal of the federal action. *See, e.g., Moses H. Cone Hospital v. Mercury Constr. Corp.,* 460 U.S. 1 (1983).

which the claimant need not demonstrate that the manufacturer was negligent or that the vaccine was defective. Furthermore, it reduces the difficulty of establishing causation. *Id.* at § 300aa-11. Under the Act compensation may be available for unreimbursable expenses, pain and suffering, loss of earnings, reasonable attorneys' fees, and other costs incurred in pursuing a claim. *Id.* at § 300aa-15. Petitioners elected not to present a claim under the Act and attempted to seek recovery through the civil tort system. Others remain free to seek redress under the Act.

CONCLUSION

For all the foregoing reasons, the Petition for Writ of Certiorari should be denied.

Respectfully submitted,

Dated: October 14, 1992

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APPENDIX

Rule 29.1 Listing

Merck & Co., Inc. Subsidiaries:

Banyu Pharmaceutical Co., Limited

A.S.C. Service Co., Ltd.

Nippon Merck-Banyu Co., Limited

Merck & Co., Inc. Joint Ventures:

Amrad Pharmaceuticals Pty. Ltd.

The du Pont Merck Pharmaceutical Company

Istituto di Ricerche di Biologia Molecolare S.p.A.

Johnson & Johnson Merck Consumer Pharmaceuticals Company

Laboratories Prosalud, S. de R.L. de C.V.

Maquifar S. de R.L. de C.V.

Prodome Quimica e Farmaceutica Ltda.